	Submissions to EPA's Request for Input on Formaldehyde Workshop	
	Topics	**Speaker**
1	Jackson Morrill, American Chemistry Council Formaldehyde Panel	
	On behalf of the American Chemistry Council Formaldehyde Panel, I submitted a letter to EPA's David Bussard by e-mail on November 22, 2013 that represents our response to this survey. In the letter, we describe in some detail the following suggested topics: **Theme:** Epidemiological research examining the potential association between formaldehyde exposure and lymphohematopoietic cancers (leukemia and lymphomas) *Topic #1:* Evidence of Lymphohematopoietic Cancers from Epidemiological Studies *Topic #2:* Characterization of Formaldehyde Exposure from Epidemiological Studies **Theme:** Mechanistic evidence relevant to formaldehyde inhalation exposure and these types of cancers T*opic #1:* Pharmacokinetics of Formaldehyde *Topic #2:* Defining the mode of action for lymphohematopoietic cancers **Theme:** Evidence pertaining to the influence of formaldehyde that is produced endogenously (by the body during normal biological processes) on the toxicity of inhaled formaldehyde, and implications for the health assessment *Topic #*1: Consideration of Endogenous Formaldehyde Production in Dose-Response Modeling **Theme:** Integration of the Scientific Evidence for the Plausibility of Lymphohematopoietic Cancer Following Formaldehyde Exposure *Topic #*1: What are possible approaches that may integrate the data and resolve differences in interpretation of the scientific evidence between experts? (See ACC Formaldehyde Panel letter to David Bussard, sent to him by e-mail on November 22, 2013)	Theme: Epidemiologic research Topic #1: Harvey Checkoway, David Savitz, Aaron Blair, Laura Beane Freeman Topic #2: Harvey Checkoway, Patricia Stewart, Peter Lees Theme: Mechanistic evidence Topic #1: Harvey Clewell, Rory conolly, Mel Andersen, Paul Schlosser, James Swenberg Topic #2: Luoping Zhang, Martyn Smith, Richard Irons, Richard Albertini, Michael Thirman, James Swenberg Theme: Endogenous formaldehyde Topic #1: James Swenberg, Thomas Starr, Harvey Clewell, Jennifer Jinot, Ravi Subramanium Theme: Integration of evidence Topic #1: Paulo Boffetta, Lorenz Rhomberg, Hans-Olav Adami, Ivan Rusyn, Jonathan Samet
2	Dale Hattis, Clark University	
		Dale Hattis, Clark University Formaldehyde carcinogenesis References provided.
3	Lorenz Rhomberg, Gradient	
	Integration across epidemiology, animal bioassays, mode of action, and kinetics to address weight of evidence across lines for potential human leukemogenicity of formaldehyde. The issues for formaldehyde are not just about the individual lines of evidence but rather about how the different lines do (or do not) come together into a single mutually consistent interpretation of the plausible means for a human leukemogenic response. The aim of the assessment in the end is to conduct such a weight-of-evidence analysis, and questions about integration have been central to the NAS review of the earlier EPA draft assessment. I have led an effort to develop the Hypothesis-Based Weight of Evidence approach to rigorous and transparent integration of evidence, and I have a major publication applying it to this exact issue (Rhomberg, Bailey, Goodman, Hamade, Mayfield. 2011. Crit Rev Toxicol 41(7):555-621. open access).	Lorenz R. Rhomberg, PhD FATS Gradient 20 University Road, Cambridge MA 02138 lrhomberg@gradientcorp.com 617.395.5552 Expertise in risk assessment, weight-of-evidence methods, toxicology, pharmacokinetics, quantitative dose-response assessment, cross species extrapolation.

4	David Coggon, University of Southampton	
		My team has recently completed extended follow-up of a cohort of 14,008 male chemical workers at six factories in England and Wales, with more than 2000 additional deaths since the last published follow-up. As well as a person-years analysis of mortality, we have conducted a nested case-control study that included 45 men with incident or fatal myeloid leukaelmia and 450 controls. We plan to submit a paper for publication within the next week. The study was funded by the Colt Foundation, a charity unconnected with formaldehyde or the chemical industry. If you wish, I would be pleased to present the findings of our study at the workshop, although I would need funding for travel. The last report of the study was: Coggon D, Harris EC, Poole J, Palmer KT. Extended follow-up of a cohort of British chemical workers exposed to formaldehyde. J Natl Cancer Inst 2003;95:1608-15 I was a member of the IARC monograph group on formaldehyde in 2004.
5	Kenny Crump, NONE	
		Kenny S. Crump (myself), no affiliation quantitative risk assessment provided references
6	Thomas Starr, TBS Associates	
	Bounding Low-Dose Cancer Risks When Endogenous Exposure Is a Contributing Factor The conventional approach to quantitative risk assessment does not consider contributions to risk from endogenous sources. Promutagenic DNA adducts arising from both endogenous and exogenous formaldehyde sources have been detected and quantified in target and non-target tissues of rats and monkeys exposed to formaldehyde by inhalation. A novel "bottom-up" approach for bounding low-dose risks when endogenous exposures are present has been proposed (Starr and Swenberg, 2013), and its use with steady-state target tissue concentrations of formaldehyde-DNA adducts as an internal dose metric produces upper bound estimates of low-dose risk that are far smaller than	James A. Swenberg, PhD, DVM, and Kenan Distinguished Professor Department of Environment Sciences & Engineering 253c Rosenau Hall, Campus Box 7431 Chapel Hill, NC 27599 USA Expertise: DNA adducts, cancer, formaldehyde Provided Relevant publications: Thomas B. Starr, PhD and

	those produced by EPA's conventional "top-down" analyses of human and animal cancer data vs. airborne formaldehyde concentration. These alternative estimates merit full and careful consideration in the IRIS toxicological review of formaldehyde.	Principal TBS Associates 7500 Rainwater Road Raleigh NC 27615-3700 USA Expertise: dose response modeling, cancer, formaldehyde, quantitative risk assessment Provided Relevant publications: Greg Paoli, MASc, Principal Risk Scientist Risk Sciences International 55 Metcalfe Street Suite 700 Ottawa ON K1P 6L5 Expertise: quantitative risk assessment Also a member of the Science Panel for the Alliance for Risk Assessment (ARA) Workshop VI Case Study: Endogenous Formation Implications for Formaldehyde Carcinogenicity. 28 May 2013. USEPA, Crystal City VA. Daniel Krewski, PhD University of Ottawa Ravi Subramaniam, USEPA Paul White, USEPA Dave Bussard, USEPA Jennifer Jinot, USEPA
7	Unknown	
		"Luoping Zhang, PhD. Adjunct Professor, Division of Environmental Health Sciences University of California Berkeley School of Public Health Expertise: molecular mechanisms of bone marrow toxicity caused by formaldehyde; biomarkers of these exposures Provided Relevant publications: "Martyn Smith, PhD Professor of Toxicology, Division of Environmental Health Sciences

		University of California Berkeley School of Public Health Expertise: molecular toxicology, biomarkers of exposure Provided Relevant publications: "Ronald Melnick Indepedent Consultant, Ron Melnick Consulting LLC Expertise: toxicology, molecular biology Provided Relevant publications:
8	Stewart Holm, American Forest & Paper Association	
	Evidence Based Data Integration or Weight of the Evidence Evaluation - This topic is consistent with the goals EPA has set forth in the application of systematic review methodology. It is very important for the wealth of data that is available for formaldehyde. Conflicting studies should be evaluated transparently and a decision should be made if important Hill criteria elements are sufficient to judge an endpoint causal or if a positive finding is more likely due to chance. Reaching conclusions on key endpoints should be a reasonable goal for this workshop.	Evidence-based integration: Lorenz Rhomberg, Gradient, PB-PK, Decision Analysis Hans-Olav Adami, Harvard Epidemiology: Laura Bean Freeman, NCI; James Collins, Dow; Harvey Checkoway, U. of WA; Jack Mandell, Exponent Mechanistic Evidence: Rory Conolly, EPA; Rusty Thomas, EPA; Paul Schlosser, EPA; Tom Starr, TBS & Associates; Melvin Anderson, Hamner; James Swenberg, U. of NC; Ivan Rusyn, U. of NC; Richard Corely, Battelle; Jeff Schroeter, Applied Research Associates; Gunter Speit, U. of Ulm Implications of Endogenous Formadehyde: Paul White, EPA; Ravi Subramanium, EPA; James Swenberg; Tom Starr; Rusty Thomas; Harvey Clewell, Hamner; David Doorman, NC State U.; Annie Jarabek, EPA
9	Nancy Beck, ACC	
	Please see email that was sent 11/22/2013 to Dave Bussard. The note below says information can be sent to the docket, however EPA has not provided any information regarding how to find this docket, what its number is, or where it is located. In addition, EPA has not even provided the name of an individual to contact regarding this workshop. I have sent a note to David Bussard at EPA with ACC comments. The email was sent 11/22/2013, in hopes that David Bussard is	

	the correct point of contact.	
10	David Eastmond, University of California, Riverside	
	I would suggest including a presentation providing an overview of chemical and radiation-induced leukemogenesis and the agents known to induce leukemia in humans.	David A. Eastmond University of California, Riverside
11	American Chemistry Council	